Docket No. BIO5023USNP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Assaf Govari	Confirmation No.:	3322
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Title	:	CALIBRATION DATA COMPARISON		
Art Unit	:	3737	Examiner :	James M. Kish

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(Date of Transmission)

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APPEAL BRIEF

i. Real Party in Interest

Biosense Webster, Inc., a California Corporation, is the real party in interest.

ii. Related Appeals and Interferences

None.

iii. Status of Claims

Claims 23-37 are pending in the case. Claims 1-22 had been withdrawn by Response to Restriction Requirement filed January 9, 2007. Claims 22-37 have been finally rejected on October 17, 2007 and this Appeal is taken from these claims.

iv. Status of Amendments

No Amendments have been filed after this Final Rejection dated October 17, 2007.

v. Summary of Claimed Subject Matter

As fully supported in Applicant's Specification, for example, FIGS. 1 – 6, Claim 23 of Applicant's claimed present invention is directed toward an apparatus 10 comprising a device 20 (FIGS. 1-3), 600 (FIG. 6) adapted to be placed into a patient wherein the device 20, 600 comprises a position sensor 28, 602 (FIG. 6) and a memory 91, 530 (FIG. 5) which stores calibration data indicative of a deviation, at each of a plurality of frequencies, of an actual sensitivity of the position sensor 28, 602 from a characteristic sensitivity 405 (FIG. 4) of the position sensor 28, 602. Specification Page 11, Line 23-Page 18, Line 9; Page 16, Lines 13-24 and Page 17, Line 24- Page 18, Line18. The characteristic sensitivity 405 of the position sensor 28, 602 is based on a pre-determined characteristic curve 405 (FIG. 4). Specification Page 16, Lines 13-24. The deviation stored in the memory 91, 530 is used to account for minor errors not detectable by the characteristic curve 405. Specification, Page 16, Line 13 – Page 17, Line 23.

Claim 34 of Applicant's claimed present invention is directed toward an apparatus 10 for position determination comprising a plurality of radiator coils adapted to generate fields at one or more frequencies and a device 20 (FIGS. 1-3), 600 (FIG. 6) adapted to be placed into a patient. Specification Page 13, Lines 18-23 and Specification Page 11, Line 23-Page 18, Line 9. The device 20 (FIGS. 1-3), 600 (FIG. 6) comprises a position sensor 28, 602 (FIG. 6) and a memory 91, 530 (FIG. 5) adapted to store calibration data

indicative of a deviation at each of a plurality of frequencies of an actual sensitivity of the position sensor 28, 602 from a characteristic sensitivity 405 (FIG. 4) of the position sensor 28, 602. Specification Page 11, Line 23-Page 18, Line 9; Page 16, Lines 13-24 and Page 17, Line 24- Page 18, Line18. The characteristic sensitivity 405 of the position sensor 28, 602 is based on a pre-determined characteristic curve 405 (FIG. 4). Specification Page 16, Lines 13-24. The deviation stored in the memory 91, 530 is used to account for minor errors not detectable by the characteristic curve 405. Specification, Page 16, Line 13 – Page 17, Line 23.

vi. Grounds of Rejection to be Reviewed on Appeal

1. Claims 23-24 and 26-37 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,266,551 (Osadchy et al.).

2. Claim 25 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Osadchy in view of U.S. Patent No. 6,233,476 (Strommer et al.).

vii. Argument

1. The rejection of Claims 23-24 and 26-37 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,266,551 (Osadchy et al.) is improper and without basis and should be overruled.

Rejections under 35 USC §102 are proper only when the claimed subject matter is identically disclosed or described in the prior art. *In re Arkley*, 59 CCPA 804, 455 F. 2d 586, 587, 172 USPQ 524, 526 (1972). Thus, in order to constitute an anticipation, all material elements recited in a claim must be found in one unit of prior art. *Soundscriber Corp. v. United States*, 360 F.2d 954,960, 148 USPQ 298, 301 (Ct. Cl. 1966).

Turning now to the prior art reference, Osadchy et al. is directed toward a catheter calibration and usage monitoring system for pre-calibrating a probe at the time of

manufacture, so as to measure and compensate for variations in the positions, orientations and games of the coils of a probe. The relevance of Osadchy et al. with respect to Applicant's present invention is addressed in Applicant's own Specification, for example, Page 1, Line 23 – Page 2, Line 8 and Page 13, Line 17 – Page 14, Line 2. It is important to note that the Osadchy et al. system and method does not in any way address using a memory which stores calibration data indicative of a deviation (for a position sensor), at each of a plurality of frequencies, of an actual sensitivity of the position sensor from a characteristic sensitivity of the position sensor, wherein the characteristic sensitivity of the position sensor is based on a pre-determined characteristic curve, and wherein the deviation stored in the memory is used to account for minor errors not detectable by the characteristic curve.

As a matter of fact, it is the Osadchy et al. system and method that is used to establish the characteristic sensitivity curve which is one of the material elements associated with the Applicant's claimed present invention of Claims 23 and 34, yet not taught, suggested or inferred in Osadchy. Accordingly, this material element of Applicant's claimed invention of Claims 23 and 34 is completely absent from the teachings of Osadchy.

Moreover, Osadchy et al. does not at all describe the material element of using a deviation to account for minor errors not detectable by the characteristic curve and stored in the memory of the system and method of Applicant's present invention of Claims 23 and 34.

Thus, it is clear that Osadchy et al. fails to disclose material elements recited in Applicant's Claims 23 and 34 and could never anticipate these claims by law.

2. The rejection of Claim 25 under 35 U.S.C. § 103(a) as being unpatentable over Osadchy in view of U.S. Patent No. 6,233,476 (Strommer et al.) is improper and without basis and should be overruled.

A claimed invention is unpatentable if the differences between it and the prior art "are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103(a) (Supp. 1998); *see Graham v. John Deere Co.*, 383 U.S. 1, 14, 148 USPQ 459, 465 (1966). The ultimate determination of whether an invention is or is not obvious is a legal conclusion based on underlying factual inquiries including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the prior art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness. *See Graham*, 383 U.S. at 17-18, 148 USPQ at 467; *Miles Labs, Inc., Inc. v. Shandon Inc.*, 997 F.2d 870, 877, 27 USPQ2d 1123, 1128 (Fed. Cir. 1993).

The invention being claimed in Claim 25 of Applicant's claimed present invention (which depends from Claim 24) is an apparatus comprising a device (adapted to be incorporated in a capsule) which is adapted to be placed into a patient wherein the device comprises a position sensor and a memory which stores calibration data indicative of a deviation, at each of a plurality of frequencies, of an actual sensitivity of the position sensor from a characteristic sensitivity of the position sensor, wherein the characteristic sensitivity of the position sensor is based on a pre-determined characteristic curve, and wherein the deviation stored in the memory is used to account for minor errors not detectable by the characteristic.

Osadchy et al. disclose a catheter calibration and usage monitoring system for pre-calibrating a probe at the time of manufacture, so as to measure and compensate for variations in the positions, orientations and games of the coils of a probe. The relevance of Osadchy et al. with respect to Applicant's present invention is addressed in Applicant's own Specification, for example, Page 1, Line 23 – Page 2, Line 8 and Page 13, Line 17 – Page 14, Line 2.

It is important to note that the Osadchy et al. system and method does not in any way address using a memory which stores calibration data indicative of a deviation (for a position sensor), at each of a plurality of frequencies, of an actual sensitivity of the position sensor from a characteristic sensitivity of the position sensor, wherein the characteristic sensitivity of the position sensor is based on a pre-determined characteristic curve, and wherein the deviation stored in the memory is used to account for minor errors not detectable by the characteristic curve.

As a matter of fact, it is the Osadchy et al. system and method that is used to establish the characteristic sensitivity curve of Applicant's claimed present invention of Claim 25, yet not taught, suggested or inferred in Osadchy et al. Clearly, Applicant's claimed invention of Claims 25 is an improvement over the prior art since it specifically uses the Osadchy et al. system and method in order to establish a characteristic sensitivity curve.

Moreover, Osadchy et al. does not at all describe, suggest or even infer using a deviation to account for minor errors not detectable by the characteristic curve and stored in the memory of the system and method of Applicant's present invention of Claim 25. Nor does Osadchy et al. describe, suggest or even infer a device (adapted to be incorporated in a capsule) which is adapted to be placed into a patient such as distinctly claimed in Applicant's present invention of Claim 25.

Not only is the scope and content of this prior art reference limited in its teachings, but there are significant differences from the teachings of Osadchy et al. when compared to the novel apparatus features and method steps (as outlined above) of Applicant's claimed present invention. Therefore, one skilled in the art would not be lead by the teaching of Osdadchy et al. to experiment with its calibration system. Thus, contrary to the Examiner's assertions, Osadchy et al. is actually evidence of the non-obvious of the present invention.

See *Graham*, 383 U.S. at 17-18, 148 USPQ at 467; *Miles Labs, Inc., Inc. v. Shandon Inc.*, 997 F.2d 870, 877, 27 USPQ2d 1123, 1128 (Fed. Cir. 1993).

Additionally, there is nothing in Osadchy et al. that indicates that a skilled artisan would have been motivated, where calibrating a device which is adapted to be incorporated in a capsule was required, to provide an apparatus comprising a device (adapted to be incorporated in a capsule) which is adapted to be placed into a patient wherein the device comprises a position sensor and a memory which stores calibration data indicative of a deviation, at each of a plurality of frequencies, of an actual sensitivity of the position sensor from a characteristic sensitivity of the position sensor, wherein the characteristic sensitivity of the position sensor is based on a pre-determined characteristic curve, and wherein the deviation stored in the memory is used to account for minor errors not detectable by the characteristic. Osadchy et al. simply does not describe nor suggest this combination. It is clear that there is no incentive in Osadchy et al. to use such a combination. Therefore, unless a Declaration under 37 C.F.R. § 1.107(b) is submitted by the Examiner to support this argument, it is not factually supported by the record and may not be the basis for a rejection under 35 U.S.C. § 103. See In re Wagner and Folkers, 152 U.S.P.Q. 552, 559 (CCPA 1967).

According to the Examiner's argument, the combination of Osadchy et al. with Strommer et al. in the rejection was directed toward providing motivation for modifying the structure of Osadchy et al. thereby providing a *prima facie* case of obviousness. However, neither Strommer et al. in combination with Osadchy et al. render the present invention as claimed obvious.

Although Strommer et al. is directed toward a medical positioning system that uses a housing in the shape of a capsule, it is important to note that the capsule-shaped housing is distinctly used for a magnetic detection probe and a biometric unit. This is far removed from the capsule distinctly claimed by Applicant's claimed present invention of Claim 25 wherein the capsule is used for a position sensor in conjunction with a memory which stores calibration data indicative of a deviation, at each of a plurality of

frequencies, of an actual sensitivity of the position sensor from a characteristic sensitivity of the position sensor, wherein the characteristic sensitivity of the position sensor is based on a pre-determined characteristic curve, and wherein the deviation stored in the memory is used to account for minor errors not detectable by the characteristic. There is not even a hint in the Strommer et al. reference, that its capsule-shaped housing for a magnetic detection probe and a biometric unit could ever be used in such a manner.

Thus, there are no relevant teachings in either Osadchy et al. or Strommer et al., either alone or in combination with each other that would ever lead one of ordinary skill in this field to arrive at the Applicant's claimed present invention of Claim 25.

The claimed present invention of Applicant's Claim 25 does not use or claim Strommer et al.'s capsule-shaped housing for a magnetic detection probe and a biometric unit. Accordingly, Strommer et al. clearly teaches away from the apparatus features set forth in Claim 25 in which the Applicant is claiming. Thus at the time of Applicant's invention, the art actually taught away from the Applicants' invention. Therefore, Strommer et al. taught away from the invention as claimed, and therefore, cannot rightly be combined with Osadchy et al. to render the present invention obvious.

Accordingly, there is not only no suggestion or disclosure in Osadchy et al. or Strommer et al. for making the claimed present invention of Applicant's invention, but also, significant differences exist between these limited teachings and Applicant's present invention as claimed. The only suggestion to combine the features of an apparatus comprising a device (adapted to be incorporated in a capsule) which is adapted to be placed into a patient wherein the device comprises a position sensor and a memory which stores calibration data indicative of a deviation, at each of a plurality of frequencies, of an actual sensitivity of the position sensor from a characteristic sensitivity of the position sensor, wherein the characteristic sensitivity of the position sensor is based on a pre-determined characteristic curve, and wherein the deviation stored in the memory is used to account for minor errors not detectable by the characteristic is provided by the Applicant's own Specification. Therefore, these prior art references are being improperly

applied by the Examiner, using hindsight reconstruction to pick and choose elements from these references, in the face of contrary teachings in each of these references.

The PTO has the burden under section 103 of establishing a *prima facie* case of obviousness. This burden can only be satisfied by a legal conclusion based on underlying factual inquiries. See *KSR Int'l Co. v. Teleflex, Inc.,* 550 U.S.___, 82 USPQ2d 1389 (2007). Accordingly, it is clear that these references are of limited scope and content and provide teachings that are significantly different from Applicant's claimed present invention of a Claim 25.

Additionally, even applying ordinary skill and common sense in view of the teachings of Osadchy et al. and Strommer et al., it is evident that one of ordinary skill in this field would not be able to arrive at the novel and non-obvious combination of apparatus features as set forth in Applicant's claimed present invention of Claim 25. Accordingly, Applicants respectfully submit that a *prima facie* case of obviousness has not been established by the PTO. Therefore, Applicant respectfully requests withdrawal of the rejection of Claim 25.

Therefore, based on the reasons outlined above, it is clear that these rejections are without merit and should be overruled.

Respectfully submitted,

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viii. **Claims Appendix**

Claim 1. (Withdrawn) A method for calibrating, comprising:
receiving, for each of a plurality of frequencies, an indication of a characteristic sensitivity of a position sensor for placement in a patient;
measuring an actual sensitivity of the position sensor at each of the plurality of frequencies; and
determining, at each of the plurality of frequencies, calibration data indicative of a deviation of the actual sensitivity from the characteristic sensitivity.

Claim 2. (Withdrawn) The method according to claim 1, wherein determining the calibration data at each of the plurality of frequencies comprises calculating by subtraction a difference between the actual sensitivity and the characteristic sensitivity.

Claim 3. (Withdrawn) The method according to claim 1, wherein determining, at each of the plurality of frequencies, the calibration data indicative of the deviation comprises expressing the deviation as a proportion of the characteristic sensitivity.

Claim 4. (Withdrawn) The method according to claim 1, wherein determining, at each of the plurality of frequencies, the calibration data indicative of the deviation comprises representing the deviation in a non-linear manner with respect to the plurality of frequencies.

Claim 5. (Withdrawn) The method according to claim 1, wherein the position sensor includes a plurality of coils, and wherein determining the calibration data, at each of the plurality of

frequencies, comprises determining the calibration data for each of the plurality of coils.

Claim 6. (Withdrawn) The method according to claim 1, wherein the position sensor includes at least one coil, and wherein determining the calibration data, at each of the plurality of frequencies, comprises determining the calibration data responsive to an actual gain and a characteristic gain of the coil.

Claim 7. (Withdrawn) The method according to claim 1, wherein the position sensor includes at least one coil, and wherein determining the calibration data, at each of the plurality of frequencies, comprises determining the calibration data responsive to at least one of: a position of the coil within the position sensor and an orientation of the coil within the position sensor.

Claim 8. (Withdrawn) The method according to claim 1, wherein the position sensor is incorporated in a device for placement within the patient, and wherein determining the calibration data, at each of the plurality of frequencies, comprises determining the calibration data responsive to at least one of: a position of the position sensor within the device and an orientation of the position sensor within the device.

Claim 9. (Withdrawn) The method according to claim 1, comprising storing the calibration data in the position sensor.

Claim 10. (Withdrawn) A method for determining a position, comprising:
placing a position sensor in a patient;
generating one or more fields at one or more respective frequencies;
generating one or more position signals, responsive to the respective fields and a position and an orientation of the position sensor;

retrieving, for at least one of the one or more frequencies, a stored value of a deviation of an actual sensitivity of the position sensor from a characteristic sensitivity of the position sensor;

determining, for the at least one of the one or more frequencies, a correction to the respective position signal, responsive to the respective position signal and the value of the deviation; and

determining the position of the position sensor, responsive to the one or more position signals and the correction.

Claim 11. (Withdrawn) The method according to claim 10, wherein determining the correction, for the at least one of the one or more frequencies, comprises adding the value of the deviation to the respective position signal.

Claim 12. (Withdrawn) The method according to claim 10, wherein the deviation is expressed as a proportion of the characteristic sensitivity, and wherein determining the correction, for the at least one of the one or more frequencies, comprises determining the correction responsive to the respective position signal and the proportion.

Claim 13. (Withdrawn) The method according to claim 10, wherein the deviation is represented in a non-linear manner with respect to the one or more frequencies, and wherein determining the correction, for the at least one of the one or more frequencies, comprises determining the correction responsive to the respective position signal and the value of the deviation represented in the non-linear manner.

Claim 14. (Withdrawn) Apparatus for calibrating a position sensor for placement in a patient, the apparatus comprising:

a test fixture, adapted to hold the position sensor in a known position and orientation;

a plurality of radiator coils, adapted to generate fields at a plurality of frequencies; and

a computer, adapted to:

receive, for each of the plurality of frequencies, an indication of a characteristic sensitivity of the position sensor,

measure an actual sensitivity of the position sensor, responsive to the fields generated at each of the plurality of frequencies, and

determine, at each of the plurality of frequencies, calibration data indicative of a deviation of the actual sensitivity from the characteristic sensitivity.

Claim 15. (Withdrawn) The apparatus according to claim 14, wherein the computer is adapted to determine the calibration data, at each of the plurality of frequencies, by calculating by subtraction a difference between the actual sensitivity and the characteristic sensitivity.

Claim 16. (Withdrawn) The apparatus according to claim 14, wherein the computer is adapted to determine, at each of the plurality of frequencies, the calibration data indicative of the deviation by expressing the deviation as a proportion of the characteristic sensitivity.

Claim 17. (Withdrawn) The apparatus according to claim 14, wherein the computer is adapted to determine, at each of the plurality of frequencies, the calibration data indicative of the deviation by representing the deviation in a non-linear manner with respect to the plurality of frequencies.

Claim 18. (Withdrawn) The apparatus according to claim 14, wherein the position sensor includes a plurality of coils, and wherein the computer is adapted to determine, at each of the plurality of frequencies, the calibration data for each of the plurality of coils.

Claim 19. (Withdrawn) The apparatus according to claim 14, wherein the position sensor includes at least one coil, and wherein the computer is adapted to determine the calibration data, at each of the plurality of frequencies, responsive to an actual gain and a characteristic gain of the coil.

Claim 20. (Withdrawn) The apparatus according to claim 14, wherein the position sensor includes at least one coil, and wherein the computer is adapted to determine the calibration data, at each of the plurality of frequencies, responsive to at least one of: a position and of the coil within the position sensor an orientation of the coil within the position sensor.

Claim 21. (Withdrawn) The apparatus according to claim 14, wherein the position sensor is incorporated in a device for placement in the patient, and wherein the computer is adapted to determine the calibration data, at each of the plurality of frequencies, responsive to at least one of: a position of the position sensor within the device and an orientation of the position sensor within the device.

Claim 22. (Withdrawn) The apparatus according to claim 14, wherein the computer is adapted to store the calibration data in the position sensor.

Claim 23. (Previously Presented) Apparatus comprising a device adapted to be placed into a patient, the device comprising:

a position sensor; and

a memory, which stores calibration data indicative of a deviation, at each of a plurality of frequencies, of an actual sensitivity of the position sensor from a characteristic sensitivity of the position sensor, wherein the characteristic sensitivity of the position sensor is based on a pre-determined characteristic curve, and wherein the deviation stored in the memory is used to account for minor errors not detectable by the characteristic curve.

Claim 24. (Original) The apparatus according to claim 23, wherein the device is adapted to be incorporated in an elongate probe.

Claim 25. (Original) The apparatus according to claim 23, wherein the device is adapted to be incorporated in a capsule, adapted to be placed in the patient.

Claim 26. (Original) The apparatus according to claim 23, wherein the deviation includes a difference between the actual sensitivity and the characteristic sensitivity, determined using subtraction, and wherein the memory is adapted to store the calibration data indicative of the difference.

Claim 27. (Original) The apparatus according to claim 23, wherein the deviation is expressed as a proportion of the characteristic sensitivity, and wherein the memory is adapted to store the calibration data indicative of the proportion.

Claim 28. (Original) The apparatus according to claim 23, wherein the deviation is represented in a non-linear manner with respect to the plurality of frequencies, and wherein the memory is adapted to store the calibration data indicative of the non-linear representation of the deviation.

Claim 29. (Original) The apparatus according to claim 23, wherein the position sensor comprises at least one coil.

Claim 30. (Original) The apparatus according to claim 29, wherein the at least one coil comprises a plurality of coils, and wherein the memory is adapted to store, at each of the plurality of frequencies, the calibration data for each of the plurality of coils.

Claim 31. (Original) The apparatus according to claim 29,
wherein the actual sensitivity of the position sensor is indicative of an actual gain of the coil,
wherein the characteristic sensitivity of the position sensor is indicative of a characteristic gain of the coil, and
wherein the memory is adapted to store the calibration data indicative of a deviation, at each of the plurality of frequencies, of the actual gain from the characteristic gain.

Claim 32. (Original) The apparatus according to claim 29, wherein the calibration data is indicative of at least one of: a position of the coil within the position sensor and an orientation of the coil within the position sensor.

Claim 33. (Original) The apparatus according to claim 29, wherein the calibration data is indicative of at least one of: a position of the position sensor within the device and an orientation of the position sensor within the device.

Claim 34. (Previously Presented) Apparatus for position determination, comprising:
a plurality of radiator coils, adapted to generate fields at one or more frequencies;
a device, adapted to be placed into a patient, the device comprising:

a position sensor; and

a memory, adapted to store calibration data indicative of a deviation, at each of a plurality of frequencies, of an actual sensitivity of the position sensor from a characteristic sensitivity of the position sensor, wherein the characteristic sensitivity of the position sensor is based on a pre-determined characteristic curve, and wherein the deviation stored in the memory is used to account for minor errors not detectable by the characteristic curve,

the position sensor adapted to generate one or more position signals responsive to the respective fields and a position and an orientation of the position sensor; and

circuitry, adapted to:

receive the position signals, and

determine the position of the position sensor, responsive to the position signals and the calibration data.

Claim 35. (Original) The apparatus according to claim 34, wherein the deviation includes a difference between the actual sensitivity and the characteristic sensitivity, determined using subtraction, and wherein the memory is adapted to store the calibration data indicative of the difference.

Claim 36. (Original) The apparatus according to claim 34, wherein the deviation is expressed as a proportion of the characteristic sensitivity, and wherein the memory is adapted to store the calibration data indicative of the proportion.

Claim 37. (Original) The apparatus according to claim 34, wherein the deviation is represented in a non-linear manner with respect to the plurality of frequencies, and wherein the memory is adapted to store the calibration data indicative of the non-linear representation of the deviation.

ix. Evidence Appendix

Not Applicable.

x. Related Proceedings Appendix

Not Applicable.